UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,663	02/15/2002	Ho-Youn Kim	1599-0213P	4710

2292 7590 01/30/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,663	KIM ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

II. Claims 1-17 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 2-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **rheumatoid arthritis**, classified in Class 424, subclass 486.

2. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **insulin dependent diabetes mellitus** classified in Class 424, subclass 486.

3. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **uveitis** classified in Class 424, subclass 486.

4. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **multiple sclerosis**, classified in Class 424, subclass 486.

5. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **autoimmune thyroiditis**, classified in Class 424, subclass 486.

6. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **autoimmune hepatitis** classified in Class 424, subclass 486.

7. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **interstitial pneumonitis**, classified in Class 424, subclass 486.

8. Claims 2-3, and 5-7, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers capable of reducing autoimmune response wherein the autoimmune disease is **glomerulonephritis,** classified in Class 424, subclass 486.

9. Claims 9-10, and 12-15, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers entrapping autoimmune a specific autoimmune antigen capable of reducing autoimmune response wherein the autoimmune disease is **rheumatoid arthritis and collagen induced arthritis,** classified in Class 424, subclass 486, and 184.1.

10. Claims 9-10, and 12-15, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers entrapping autoimmune a specific autoimmune antigen capable of reducing autoimmune response wherein the autoimmune disease is **multiple sclerosis,** classified in Class 424, subclass 486, and 184.1.

11. Claims 9-10, and 12-15, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers entrapping autoimmune a specific autoimmune antigen capable of reducing autoimmune response wherein the autoimmune disease is **experiential autoimmune encephalomyelitis,** classified in Class 424, subclass 486, and 184.1.

12. Claims 9-10, and 12-15, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers entrapping autoimmune a specific autoimmune antigen capable of reducing autoimmune response wherein the autoimmune disease is **insulin dependent diabetes mellitus and experimental diabetes mellitus,** classified in Class 424, subclass 486, and 184.1.

13. Claims 9-10, and 12-15, drawn to a method of treating a specific autoimmune disease which comprises administering orally to a mammal particles of biodegradable polymers entrapping autoimmune a specific autoimmune antigen capable of reducing autoimmune response wherein the autoimmune disease is **uveitis,** classified in Class 424, subclass 486, and 184.1.

14. Claim 16, drawn to a composition for inducing tolerance for autoimmune disease, which comprises as an active ingredient particles of biodegradable polymers capable of reducing autoimmune response, classified in classified in Class 424, subclass 486 and 184.1.

15. Claim 17, drawn to a composition for inducing tolerance for autoimmune disease, which comprises as an active ingredient particles of biodegradable polymers entrapping an a specific autoimmune antigen capable of reducing autoimmune response, classified in classified in Class 424, subclass 486 and 184.1.

Linking claim 1 will be examined along with Groups (1-8) if one of said groups is elected.

Linking claim 8 will be examined along with Groups (9-13) if one of said groups is elected.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-13 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treating a distinct disease using a distinct product differs with respect to their etiology, treatment steps and therapeutic endpoints. Therefore, they are patentably distinct.

Inventions of Groups 14-15 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed can be used in treating different disease as claimed or materially different process such as making antibody, and screening assays. Therefore, they are patentably distinct.

Inventions of Groups (14-15) and Groups (1-13) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in treating different autoimmune disease as claimed. Therefore, they are patentably distinct.

IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the

allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

VIII. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
January 26, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600